15.0 MANAGEMENT MEASURES

This chapter of the revised draft Safety Evaluation Report (DSER) contains the staff's review of management measures described by the applicant in Chapter 15 of the revised Construction Authorization Request (CAR). Management measures are defined in 10 CFR 70.4 as functions, performed by a licensee, generally on a continuing basis, that are applied to items relied on for safety (IROFS), to provide reasonable assurance that the items are available and reliable to perform their functions, when needed. As further stated in the 10 CFR 70.4 definition, management measures include configuration management (CM); maintenance; training and qualifications; procedures; audits and assessments; incident investigations; records management; and other quality assurance (QA) elements. Management measures are made applicable to the revised CAR review by 10 CFR 70.64(a)(1). For purposes of establishing quality standards, 10 CFR 70.64(a)(1) requires, in pertinent part, that the design of the proposed Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF or the facility) "must be developed and implemented in accordance with management measures, to provide adequate assurance that IROFS will be available and reliable to perform their function when needed."

In its MOX Project Quality Assurance Plan (MPQAP), Revision 2, the applicant had previously addressed the QA program description requirements (which are referenced in revised DSER Section 15.1). The staff issued an SER approving the MPQAP, including additional Duke, Cogema, Stone & Webster (DCS) clarification and commitments regarding two QA issues, on October 1, 2001 (Reference 15.1.3.6). Subsequently, DCS revised the MPQAP to address the additional clarifications and commitments, and submitted Revision 3 of the MPQAP (Reference 15.1.3.7). The staff verified that the MPQAP, Revision 3, adequately incorporated all of the DCS clarifications and commitments noted in the SER and approved the MPQAP, Revision 3, for construction activities (Reference 15.1.3.8). The staff concluded, pursuant to 10 CFR 70.23(b), that the MPQAP, as applied to all structures, systems, and components (SSCs) of the proposed facility, will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. The scope of this 10 CFR 70.23(b) finding was described in the MPQAP SER's conclusion as pertaining to the construction of the SSCs for the proposed facility, including all related design procurement and fabrication activities. As further stated in the MPQAP SER's conclusion, this finding did not pertain to any start-up testing or operation of the proposed MFFF. Accordingly, since the staff in its October 1, 2001 SER, approved the applicant's general QA program as described above, this revised DSER focuses on the additional QA elements and other management measures described in revised CAR Chapter 15, and evaluates these management measures pursuant to 10 CFR 70.64(a)(1). The objective of this revised DSER review is to determine whether the proposed management measures, together with the previously-approved MPQAP, establish a QA program which provides reasonable assurance of protection against natural phenomena and the consequences of potential accidents, as required for revised CAR approval by 10 CFR 70.23(b). For the reasons stated in the following revised DSER sections, the staff concludes, pursuant to 10 CFR 70.23(b), that the proposed management measures set forth in the revised CAR, together with the previously-approved MPQAP, establish a QA program which provides reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

The staff evaluated the information provided by the applicant for management measures by reviewing Chapter 15 of the revised CAR, other sections of the revised CAR, supplementary information provided by the applicant, and relevant documents available at the applicant's offices but not submitted by the applicant. The review of management measures was closely coordinated with the review of accident sequences described in the Safety Assessment of the Design Bases (see Chapter 5.0 of this revised DSER). Note that management measures will be applied to IROFS, and that IROFS need not be specified until the applicant submits its integrated safety analysis (ISA) summary (see 10 CFR 70.65(b)(6). Thus, the staff will perform a more detailed evaluation of management measures as part of the review of the application for a 10 CFR Part 70 license to possess and use special nuclear material (SNM), which the applicant plans to submit to the NRC if its revised CAR is approved.

The review of the applicant's description of management measures is addressed in the following sections in the order that the applicant presented them in the revised CAR, beginning with QA. The staff used Chapter 15.0 in NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," as guidance in performing the review.

15.0 MANAGEMENT MEASURES
15.1 QUALITY ASSURANCE

15.1.1 CONDUCT OF REVIEW

The staff reviewed the Quality Assurance (QA) descriptions and commitments of the applicant's revised Construction Authorization Request (CAR) for the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF or the facility) in accordance with NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide Fuel Fabrication Facility." The purpose of this review is to establish that the applicant has a plan to integrate its implementation of management measures into its approved MOX Project Quality Assurance Program (MPQAP), which is applicable to the design, fabrication, and construction of all structures, systems and components (SSCs) -- including those designated as principal SSCs (Reference 15.1.3.6). The following regulations apply specifically to QA:

- Part 21 of 10 CFR describes regulatory requirements for identifying, controlling, and reporting defects in a facility, activity, or basic component supplied to a facility, licensed under the Atomic Energy Act which could create a substantial safety hazard.

- Section 70.64(a)(1) of 10 CFR states, in pertinent part, that for quality standards, the facility design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety (IROFS) will be available and reliable to perform their function when needed.

- Section 70.64(a)(8) of 10 CFR states, in pertinent part, that the design of IROFS must provide for inspection and testing, to ensure that IROFS will be available and reliable to perform their functions when needed.

- Section 70.23(b) of 10 CFR states, as a prerequisite to revised CAR approval, that the QA program be found to provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. Section 70.23(b) of 10 CFR further states that the criteria in Appendix B ("Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," referred to hereafter as Appendix B) of 10 CFR Part 50 will be used in determining whether the QA program provides reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

In revised CAR Section 15.1, the applicant stated that the application of management measures will ensure that the principal SSCs are available and reliable to perform their intended design functions.

MPQAP, Revision 2, was submitted as the required description of a QA program that meets the general QA requirements of 10 CFR Part 50, Appendix B. The applicant has committed to compliance with the provisions of Parts I and II of American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities," as revised by the ASME NQA-1a-1995 Addenda, and U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 1.28 (Rev.3), "Quality Assurance Program Requirements (Design and

Construction)." These ASME NQA-1 and Regulatory Guide provisions are hereafter referred to as NQA-1. The staff reviewed and compared and evaluated the MPQAP against the Appendix B requirements and the NQA-1 provisions, as well as NUREG-1718 guidance. The QA areas reviewed by the staff included the applicant's descriptions in the MPQAP for organization, QA function, design control, procurement document control, instructions, procedures, and drawings, document control, control of purchased items, identification and control of items, control of special processes, inspection, test control, control of measuring and test equipment, handling, storage, and shipping, inspection, test, and operating status, nonconformances, corrective action, QA records, audits and assessments, and the applicant's provisions for continuing QA. The results of this review are documented in the MPQAP SER dated October 1, 2001 (Reference 15.1.3.6). Additional discussions on the implementation and application of the applicant's QA program description in the MPQAP, Revision 2, as supplemented by requests for additional information (RAI) responses, were held during telephone meetings and in-office reviews, particularly on the Quality Level categorization commitments including classification criteria and the categorization process. Duke Cogema Stone & Webster (DCS) incorporated all additional clarifications and commitments referred in the MPQAP SER into Revision 3 of the MPQAP (Reference 15.1.3.7). The staff reviewed the MPQAP, Revision 3, verified that it appropriately incorporated all commitments and clarifications, and approved it for construction application (Reference 15.1.3.8). In MPQAP, Revision 3, the applicant commits to invoking and complying with the applicable requirements of 10 CFR Part 21 for all design, procurement, fabrication and construction activities.

15.1.2 EVALUATION FINDINGS

Based on the staff's review of revised CAR Section 15.1,and the clarifications and commitments made by the applicant in response to NRC RAIs relevant to its QA program, the staff finds that DCS has appropriately committed to invoking the applicable 10 CFR Part 21 requirements for design, procurement, and construction. Additionally, the staff finds, pursuant to 10 CFR 70.64(a)(1), that the principal SSCs are being properly designed and developed, thus providing adequate assurance that IROFS will be available and reliable to perform their intended design functions when needed. However, as stated in revised DSER Section 15.0, the staff will perform a more detailed evaluation of management measures as part of the review of the application for a 10 CFR Part 70 license to possess and use special nuclear material (SNM), which the applicant plans to submit to the NRC if its revised CAR is approved. The staff also finds, pursuant to 10 CFR 70.64(a)(8), that the inspection and testing elements of QA are in place, so as to adequately ensure that IROFS will be available and reliable to perform their functions when needed.

Based on the above findings, together with its earlier approval of the MPQAP (References 15.1.3.6 and 15.1.3.7), the staff concludes, pursuant to 10 CFR 70.23(b), that the QA program at the proposed facility will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. The scope of this conclusion pertains to the construction of the facility's principal SSCs, and includes all related design, procurement and fabrication activities, but does not include any start-up testing or operation of the proposed facility.

15.1.3 REFERENCES

15.1.3.1 American Society of Mechanical Engineers (ASME). ASME–NQA–1–1994, "Quality Assurance Requirements for Nuclear Facility Applications," (as revised by the ASME NQA-1a-1995 Addenda). ASME: New York, New York. 1994/1995.

15.1.3.2 Code of Federal Regulations, *Title 10, Energy,* Part 21, “Reporting of Defects and Noncompliances.”

15.1.3.3 Code of Federal Regulations, *Title 10, Energy,* Part 70, "Domestic Licensing of Special Nuclear Material."

15.1.3.4 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)," *Federal Register:* Vol. 64, No. 146. pp. 41338-41357. July 30, 1999.

15.1.3.5 Nuclear Regulatory Commission (U.S.) (NRC). Regulatory Guide 1.28, Revision 3, “Quality Assurance Program Requirements (Design and Construction),” NRC: Washington, D.C. August 1985.

15.1.3.6 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, October 1, 2001.

15.1.3.7 Hastings, P., Duke Cogema Stone & Webster, letter RE Quality Assurance Program for Construction of the Mixed Oxide Fuel Fabrication Facility, March 26, 2002.

15.1.3.8 Persinko, A., U.S. Nuclear Regulatory Commission, letter to P. Hastings, Duke Cogema, Stone & Webster, RE DCS Quality Assurance Program for Construction of the Mixed Oxide Fuel Fabrication Facility, January 10, 2003.

15.0 MANAGEMENT MEASURES
15.2 CONFIGURATION MANAGEMENT

15.2.1 CONDUCT OF REVIEW

This section of the revised draft Safety Evaluation Report (DSER) contains the staff's review of the configuration management system committed to by the applicant in Chapter 15, Section 15.2 of the revised Construction Authorization Request (CAR). The objective of this review is to verify that the applicant has adequately planned for the implementation of an acceptable configuration management (CM) system which will provide reasonable assurance that the principal structures, systems, and components (PSSCs) identified by the applicant will be available and reliable to perform their safety function when needed. The review, for construction authorization, is to determine whether the applicant has adequately planned for CM to be accomplished during design and construction and whether necessary policies, personnel, procedures, and instructions will be in place to begin CM during the design and construction of the PSSCs.

The following regulations apply specifically to CM:

- Section 70.4 of 10 CFR defines the term "configuration management" as a management measure "that provides oversight and control of design information, safety information, and records of modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their functions when needed."

- Section 70.64(a)(1) of 10 CFR states, in pertinent part, that for quality standards, the MFFF design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed.

NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," (MFFF or the facility) Section 15.2.3, "Areas of Review," defines the review areas, and states that the description of the CM system should be reviewed with emphasis on the processes for documenting an established baseline configuration and controlling changes to it to preclude inadvertent degradation of safety. The review should include the applicant's descriptions of the organizational structure responsible for CM activities and the process, procedures, and documentation required for modifying structures, systems, and components (SSCs), PSSCs, and items relied on for safety (IROFS) and the supporting management measures. The review should focus on the applicant's management level controls that ensure (a) the disciplined documentation of engineering, installation, and operation of modifications; (b) the training and qualification of affected staff; (c) revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; (d) post-modification testing; and (e) operational readiness review. The review topics should include CM policy, design requirements, document control, change control, and assessments.

15.2.1.1 CM Policy

The applicant describes its overall CM system in revised CAR Section 15.2, and presents its CM policy in Section 15.2.1, which states that CM is provided for PSSCs throughout the facility design, construction, testing, operation and deactivation, to provide the means to establish and maintain a technical baseline for the facility. The applicant's CM system during design and construction is the responsibility of the Deputy Project Manager - MFFF Engineering and Construction. The CM system controls documents in accordance with quality assurance (QA) procedures for design control, document control, and records management. During the design and construction phases, the applicants's CM is, and will be, based on Section 3, "Design Control" of the MOX Project Quality Assurance Plan (MPQAP) and associated MPQAP requirements and procedures for design and construction documents and activities that establish and maintain the technical baseline. The staff reviewed these MPQAP commitments and requirements for CM, and determined that they were acceptable for construction activities, including design, procurement and fabrication. The staff review and conclusion were documented in a SER, on October 1, 2001 (Reference 15.2.3.4). Design documents and changes undergo interdisciplinary review and verification. Proper implementation is verified and reflected in the design basis documentation. The applicant will update the CM description to include details of the operational configuration management program in the license application for possession and use of special nuclear material (SNM). If the facility is licensed to operate, any changes to the CM program would be governed by 10 CFR 70.72, "Facility Changes and Change Process."

Section 15.2 of the revised CAR states that CM is applied to SSCs. The applicant addressed its commitment to CM application during design and construction and specifically describes: (1) establishing and controlling the design bases to include all SSCs, not just PSSCs and IROFS, (2) how the CM process functions for documenting the baseline configuration and controlling all changes, and (3) how it provides for change control during construction (i.e., that the same design control procedures are to be used for all SSCs, not just PSSCs and IROFS). During any construction of the proposed facility, all field changes, as-built configurations, and non-conformances will be reviewed for impact to the design basis.

In Section 15.2 of the revised CAR, the applicant describes the design documents under CM, which include calculations, safety analyses, design criteria, engineering drawings, system descriptions, technical documents, and specifications that establish design requirements. The scope of CM expands throughout the design process. During any construction, startup and operations, the scope of documents under CM would expand to include vendor, test, and inspection data, startup, test, operating and administrative procedures, and nonconformance reports. These documents will include those generated through functional interfaces with QA, maintenance, and training and qualifications of personnel. The applicant describes how the CM system is implemented through or related to other management measures and describes these interfaces and relationships.

The approved MPQAP establishes the framework for the applicants' CM system and other management measures for PSSCs (References 15.2.3.4 and 15.2.3.6). CM system records are generated and processed in accordance with the requirements of the MPQAP. Maintenance requirements are established as part of the design basis which is controlled under CM, and records provide evidence of compliance with preventative and corrective maintenance

schedules. Training and qualification of personnel is controlled in accordance with the MPQAP provisions, and will be considered part of the design basis controlled under CM. Corrective actions and changes resulting from audits, assessments, and incident investigations, will be evaluated and controlled in accordance with provisions of the MPQAP and QA procedures. Plant procedures will be controlled in accordance with the MPQAP and QA procedures, and will be reviewed for impact to the design basis.

The applicant's description of CM includes the designation of PSSCs under the QA classification and grading provisions of Section 2 of the MPQAP. The grading approach to SSC includes applying the most stringent QA controls to SSCs with the highest safety significance. All controls for all PSSCs are controlled under CM and documented in the same manner. The applicant's commitments for SSC classification and the grading process are discussed in the SER approving the MPQAP (Reference 15.2.3.4), and are incorporated in MPQAP, Revision 3 (Reference 15.2.3.6).

15.2.1.2 Design Requirements

The applicant stated that the organization structure and staffing interfaces for the CM system, for design and construction, will be administered by the MFFF Engineering organization. The lead discipline engineers will have primary technical responsibility for the work performed by their disciplines, and will be responsible for the conduct of interdisciplinary reviews. Reviews are also conducted by construction management , operations, QA and procurement personnel. The design control process will also interface with document control and records management processes controlled by QA procedures. PSSCs are designated as Quality Level-1 (QL-1) using the approved MPQAP classification process, and their associated design documents will be subject to review and verification. Analyses constituting the safety assessment of the design bases, are subject to these same requirements, and changes are evaluated to ensure consistency with the design bases. Design bases documented in CAR Chapters 5 through 11 will be consistent with those in, and flowed down from, the design requirements and basis of design documents, analyses, specifications and drawings. The CM system will capture these requirements and resulting design bases in accordance with design control, document control and records management procedures.

SSCs will be classified based on their safety significance and role in preventing or mitigating design basis accidents in accordance with the categories of QA classification described in Section 2 of the MPQAP and approved by the staff (References 15.2.3.4 and 15.2.3.6).

15.2.1.3 Document Control

Document control will be implemented in accordance with Section 6 of the MPQAP. These provisions were reviewed by the staff and found to be adequate for design and construction of the proposed facility (Reference 15.2.3.4).

15.2.1.4 Change Control

The applicant's description for control of changes to the technical baseline identifies that they are controlled under Section 3, "Design Control," of the MPQAP and associated procedures. The change control process includes technical, management and safety reviews prior to

implementation. The review process includes reviews to ensure consistency with the approved safety assessment of the design bases of principal SSCs and include provisions for appropriate reviews at the design, construction, and operations phases.

15.2.1.5 Assessments

The applicant confirms that assessments, including initial and periodic examinations of the CM system, will be conducted to determine the system's effectiveness and to correct deficiencies. The applicant committed that such assessments will be systematically planned and conducted in accordance with an overall facility audit and assessment program as described by the applicant in revised CAR Section 15.6.

The applicant also committed to updating the CM system to reflect any changes to the proposed facility made between submittal of the revised CAR and submittal of the application to possess and use SNM.

15.2.2 EVALUATION FINDINGS

In Chapter 15.2 of the revised CAR, DCS committed to implement and update its CM system at the proposed facility. Management-level policies and procedures, including a safety review of any proposed activity involving SSCs, are described that will ensure that the relationship between design requirements, construction, and facility documentation is maintained as part of a new design or change in an existing design. The administrative control will ensure that the organizational structure, procedures, and responsibilities necessary to implement CM are in place or committed to; that the design requirements and bases are documented and supported by analyses and the documentation is maintained current; that documents, including drawings, are appropriately stored and accessible; that drawings and related documents adequately describe SSCs; that procedures adequately describe how the applicant will achieve and maintain strict consistency among the design requirements, facility construction, and facility documentation; and that methods are in place for suitable analysis, review, approval, and implementation of identified changes to SSCs. The applicant described its approach to QL categorization and grading of controls for SSCs and identified the process, criteria and control to be applied. Pursuant to 10 CFR 70.64(a)(1), Quality Standards and Records, the staff finds that the applicant's proposed CM system is a management measure ensuring that the facility design is being properly developed and implemented, so as to provide adequate assurance that IROFS will be available and reliable to perform their function when needed. The applicant will describe its Operation Phase Change process, for 10 CFR 70.72 provisions, in more detail in its application for a SNM possession and use license. Accordingly, the staff concludes, pursuant to 10 CFR 70.23(b), that the CM system set forth in the MPQAP and the revised CAR is part of a QA program which will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

15.2.3 REFERENCES

15.2.3.1 Code of Federal Regulations, *Title 10, Energy,* Part 70, "Domestic Licensing of Special Nuclear Material."

15.2.3.2 Department of Energy (U.S.) (DOE). DOE–STD–1073–93–Pt.1 and –Pt.2, "DOE Standard Guide for Operational Configuration Management Program." DOE: Washington, D.C. 1993.

15.2.3.3 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register:* Vol. 64, No.146. pp. 41338–41357. July 30, 1999.

15.2.3.4 Persinko, A., U.S. Nuclear Regulatory Commission, letter to P. Hastings, Duke Cogema Stone & Webster RE DCS Quality Assurance Program for Construction of the MFFF, October 1, 2001.

15.2.3.5 Hastings, P., Duke Cogema Stone & Webster, letter to U.S. Nuclear Regulatory Commission, RE Response to Request for Additional Information (DCS-NRC-000059), August 31, 2001.

15.2.3.6 Persinko, A., U.S. Nuclear Regulatory Commission, letter to P. Hastings, Duke Cogema Stone & Webster RE DCS Quality Assurance Program for Construction of the MFFF, January 10, 2003.

15.0 MANAGEMENT MEASURES
15.3 MAINTENANCE

15.3.1 CONDUCT OF REVIEW

This section of the revised draft Safety Evaluation Report (DSER) contains the staff's review of the maintenance program committed to by the applicant in Chapter 15, Section 15.3 of the revised Construction Authorization Request (CAR). The objective of this review is to determine whether the proposed facility will have a maintenance program which will provide adequate assurance that items relied on for safety (IROFS) (other than personnel activities) will be available and reliable to perform their safety function when needed.

The following regulations apply specifically to the staff's review of the proposed maintenance program:

- Section 70.4 of 10 CFR defines the term "management measures" as including a maintenance program.

- Section 70.64(a)(1) of 10 CFR states, in pertinent part, that the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF or the facility) design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed.

- Section 70.64(a)(8) of 10 CFR states, in pertinent part, that the design of IROFS must provide for maintenance, to ensure that IROFS will be available and reliable to perform their functions when needed.

15.3.1.1 Maintenance Program

In revised CAR Section 15.3, the applicant describes and commits to implementation of a maintenance program including safety controls, surveillance/monitoring, corrective maintenance, preventive maintenance, functional testing, and work control methods, and describes the relationship of the maintenance elements to other management measures. The applicant will describe its maintenance program in more detail in the license application for possession and use of special nuclear material (SNM). Preventative maintenance activities, surveillance, and performance trending would be done to provide reasonable and continuing assurance that IROFS will be available and reliable to perform their safety functions.

15.3.1.2 Safety Controls

The applicant commits to providing safety controls by specifying maintenance requirements for calibration frequency, functional testing requirements, and replacement of specified components for IROFS.

15.3.1.3 Maintenance Elements

The applicant's description requires that surveillance and monitoring of IROFS, including instrument calibration and testing be performed at specified intervals to measure the degree to which IROFS meet performance specifications. The results of surveillances would be trended and, when indicated by potential performance degradation, preventive frequencies adjusted or other corrective action taken. Incident investigations may also identify root causes of failures related to maintenance type or frequency, and lessons learned from these investigations would be factored into the maintenance program. Procedures would prescribe compensatory measures for surveillance tests that could be performed only while equipment was out of service.

Preventive maintenance measures described by the applicant include preplanned and scheduled periodic refurbishment, overhaul, or replacement of IROFS to ensure their continued safety function. Planning would include results of surveillance and monitoring, and instrument calibration and testing.

Corrective maintenance would be performed for repair or replacement of equipment that has unexpectedly degraded or failed. Corrective maintenance would restore IROFS to acceptable performance through a planned, systematic, controlled, and documented approach for the activities.

Following initial installation, functional testing of IROFS would be performed as part of the applicant's periodic surveillance testing, and, also, after corrective or preventive maintenance or calibration to ensure that the item is capable of performing its safety function when required. The functional testing would be conducted using approved procedures, that would include compensatory measures that may be necessary while the test of equipment or systems was being conducted.

15.3.1.4 Work Control Methods

The applicant commits to maintenance-related work control methods including maintenance management and tracking, which would involve integration of maintenance activities with ongoing operations activities. Work control methods would also include appropriate interfaces with radiation protection and associated work permits, lockout/tagout requirements, and procedures.

15.3.1.5 Maintenance Relationship to Other Management Measures

The applicant's committed maintenance function will interface with the configuration management and procedure systems by obtaining the approved and controlled drawings, specifications and procedures. Personnel would be trained in the maintenance of IROFS through the training program, and records of performance trends and maintenance history would be maintained.

15.3.2 EVALUATION FINDINGS

In Chapter 15.3 of the revised CAR, Duke Cogema Stone & Webster (DCS) described and committed to implement its maintenance program to be used on IROFS and associated activities at the proposed facility. Pursuant to 10 CFR 70.64(a)(1) the staff finds that the applicant's proposed maintenance program is a management measure providing adequate assurance that IROFS will be available and reliable to perform their function when needed. Additionally, pursuant to 10 CFR 70.64(a)(8), the staff finds that the maintenance elements of QA are in place, so as to adequately ensure that IROFS will be available and reliable to perform their functions when needed. The applicant will describe its maintenance program in more detail in its application for an SNM possession and use license. Accordingly, the staff concludes, pursuant to 10 CFR 70.23(b), that the maintenance program set forth in the revised CAR is part of a Quality Assurance (QA) program which will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

15.3.3 REFERENCES

15.3.3.1 Code of Federal Regulations, *Title 10, Energy,* Part 70, "Domestic Licensing of Special Nuclear Material."

15.3.3.2 ———*.Title 10, Energy*, Section 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants."

15.3.3.3 ———.*Title 29, Labor,* Section 1910.119, "Process Safety Management of Highly Hazardous Chemicals."

15.3.3.4 ———*. Title 40, Protection of Environment*, Part 68, "Risk Management Program for Chemical Accidental Release Prevention."

15.3.3.5 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities." *Federal Register:* Vol. 54, No. 53. pp. 11590–11598. March 21, 1989.

15.3.3.6 ———*.* "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)," *Federal Register:* Vol. 64, No. 146. pp. 41338-41357. July 30, 1999.

15.3.3.7 Nuclear Regulatory Commission (U.S.) (NRC). Inspection Manual, Procedure 88025, "Maintenance and Surveillance Testing." NRC: Washington, D.C. May 23, 1984.

15.3.3.8 ———. Inspection Manual, Procedure 88062, "Maintenance and Inspection." NRC: Washington, D.C. January 1996.

15.3.3.9 ———. Regulatory Guide 1.160, Rev. 2, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants." NRC: Washington, D.C. March 1997.

15.3.3.10 Persinko, A., U.S. Nuclear Regulatory Commission, letter to P. Hastings, Duke, Cogema, Stone & Webster RE DCS Quality Assurance Program for Construction of the MOX Fuel Fabrication Facility, January 10, 2003.

15.0 MANAGEMENT MEASURES
15.4 TRAINING AND QUALIFICATION

15.4.1 CONDUCT OF REVIEW

This section of the draft Safety Evaluation Report (DSER) contains the staff's review of the training and qualification information provided by the applicant in Chapter 15, Section 15.4 of the revised Construction Authorization Request (CAR). The objective of this review is to determine whether personnel who would perform activities relied on for safety will understand, recognize the importance of, and be qualified to perform these activities in a manner that adequately protects the public; worker health and safety; and the environment. The staff evaluated the applicant's provisions for training and qualification by reviewing the revised CAR, the applicant's quality assurance (QA) program description, the Mixed Oxide (MOX) Project Quality Assurance Plan (MPQAP), responses to staff requests for additional information (RAIs) and relevant documents available at the applicant's offices but not submitted by the applicant.

The following regulations apply specifically to the staff's review of the proposed training and qualification program:

- Section 70.4 of 10 CFR defines the term "management measures" as including a training and qualification program.

- Section 70.64(a)(1) of 10 CFR states, in pertinent part, that the Mixed Oxide Fuel Fabrication Facility (MFFF or the facility) design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed.

Pursuant to NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide Fuel Fabrication Facility," Section 15.4.3, "Areas of Review," the staff's review of the proposed training and qualification program included the following areas:

- Organization and management of training.

- Analysis and identification of functional areas requiring training.

- Position training requirements.

- Development of the basis for training, including objectives.

- Organization of instruction using lesson plans and other training guides;.

- Evaluation of trainee learning.

- Conduct of on-the-job training.

- Evaluation of training effectiveness.

- Personnel qualification.

- Applicant's provisions for continuing assurance, including the needs for retraining or reevaluation of qualification.

15.4.1.1 Organization And Management Of Training

The applicant describes its training program for the operations phase of the facility in revised CAR Section 15.4 and states that training program requirements will apply to plant personnel who perform activities relied on for safety. The applicant's approved MPQAP addresses training and qualification requirements during the facility design and construction phases, including QA training of personnel for nondestructive examination, inspection and test personnel, and for auditors. The staff reviewed these MPQAP commitments and requirements for training and qualification, and determined that they were acceptable for construction activities, including design, procurement and fabrication (Reference 15.4.3.6). The applicant specifically commits to the establishment of an operational training program in accordance with its description in revised CAR Section 15.4 and will update the program information in the license application for possession and use of special nuclear material (SNM).

The applicant's training program description requires that line managers are responsible for the content and effective conduct of training for their personnel. Line managers will be given the authority to implement training and their responsibilities are included in position descriptions. The applicant's training organization will provide support with planning, directing, analyzing, developing, conducting, evaluating and controlling a systematic performance-based training process. Plant procedures will establish the requirement for indoctrination and training of personnel performing activities relied on for safety. Lesson plans, which will be used for classroom and on-the-job training, will be included in the configuration management (CM) system and will be updated based on design changes or plant modifications. Auditable training records will be maintained to support management information needs for personnel training, job performance, and qualifications.

15.4.1.2 Analysis and Identification of Functional Areas Requiring Training

The applicant will perform a needs/job analysis and identify tasks to ensure that appropriate training is provided to personnel. A task list will be developed and updated as needed, and will be reviewed as part of the systematic valuation of training effectiveness.

15.4.1.3 Position Training Requirements

The applicant will develop minimum training requirements for positions whose activities are relied on for safety. Entry-level criteria will be defined for the positions, including minimum educational, technical, and experience requirements. Initial identification of job-specific training requirements will be based on experience from MELOX and La Hague operations in France and from United States experience.

15.4.1.4 Development of the Basis for Training

The applicant will establish learning objectives that identify the training content, based on the needs/job analyses and position-specific requirements. The task list will be used to develop the desired post-training performance objectives, including the knowledge, skills and abilities that

the trainee should demonstrate; the conditions under which required actions will take place; and the standards of performance the trainee should achieve on completion of the training activity.

15.4.1.5 Organization of Instruction Using Lesson Plans and Other Training Guides

The applicant will use the learning objectives, derived from specific job performance requirements and the needs/job analysis, to develop lesson plans and other training guides. Lesson plans are approved prior to use, and are used for classroom and on-the-job training.

15.4.1.6 Evaluation Of Trainee Learning

The applicant will evaluate trainee mastery of learning objectives through observation and demonstration or oral or written tests as appropriate. Evaluations will measure the trainee's skills and knowledge of job performance requirements.

15.4.1.7 Conduct Of On-the-Job Training

The applicant's description includes requirements for on-the-job training to be performed for IROFS activities using current performance-based training materials, conducted by designated personnel who are competent in the program standards and methods of conducting the training. Completion of on-the-job training will be demonstrated by actual task performance where feasible and appropriate. When the actual task cannot be performed by the trainee, a simulation of the task is performed using the conditions encountered with task performance, including references, tools, and equipment reflecting the actual task to the extent practical.

15.4.1.8 Evaluation Of Training Effectiveness

The applicant will systematically evaluate the training program's effectiveness in producing competent employees on a periodic basis. These evaluations, will include feedback from trainees, and will identify program strengths and weaknesses, determine whether program content matches current job needs and determine if corrective actions are needed to improve the program's effectiveness. Evaluation objectives will be developed, results will be documented and changes made to procedures, practices or training materials as necessary.

15.4.1.9 Personnel Qualification

The applicant discusses its commitments for personnel qualification in revised CAR Section 15.4.9. Qualification requirements for key management positions are addressed in revised CAR Chapter 4, and are in accordance with the applicable guidance in NUREG-1718, Section 15.4.4.3, "Regulatory Acceptance Criteria." Revised CAR Chapter 4 currently stresses the organization for design and construction of the proposed facility, and the applicant will supplement this information when it submits its SNM license application to address operations and the qualifications of key plant management positions.

15.4.1.10 Applicant's Provisions For Continuing Assurance

The applicant's description of its provisions for continuing assurance of training and qualification of plant personnel include an evaluation of personnel performing activities relied on for safety to determine that they continue to understand, recognize the importance of, and have the appropriate qualifications needed to perform their activities. The evaluation may be by written or oral test, or performance evaluation. The evaluation results will be documented, and retraining or other appropriate action taken when indicated. Retraining will also be required for plant modifications, procedure changes and QA program changes when needed.

15.4.2 EVALUATION FINDINGS

In Chapter 15.4 of the revised CAR, DCS described its management measures for training and qualification to be used during the operations phase of the proposed facility. Based on that information and the discussion provided in the sections above for training and qualification, the staff finds that the personnel who perform activities relied on for safety will understand, recognize the importance of, and be qualified to perform these activities in a manner that will adequately protect the public, worker health and safety, and the environment. The applicant will establish an operational training program in accordance with its description in revised CAR Section 15.4. Pursuant to 10 CFR 70.64(a)(1), the staff finds that the applicant's proposed training and qualification program is a management measure providing adequate assurance that IROFS will be available and reliable to perform their function when needed. The applicant will update the training program description for operations activities in its application for a 10 CFR Part 70 SNM possession and use license. Accordingly, the staff concludes, pursuant to 10 CFR 70.23(b), that the management measures for training and qualification set forth in the MPQAP and the revised CAR is part of a QA program which will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

15.4.3 REFERENCES

15.4.3.1 American Society of Mechanical Engineers (ASME). ASME–NQA–1–1994, "Quality Assurance Requirements for Nuclear Facility Applications." ASME: New York, New York. 1994.

15.4.3.2 Code of Federal Regulations, *Title 10, Energy,* Part 70, "Domestic Licensing of Special Nuclear Material."

15.4.3.3 ———. *Title 10, Energy,* Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations."

15.4.3.4 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material, (10 CFR Part 70)." *Federal Register:* Vol. 64, No. 146. pp. 41338-41357. July 30, 1999.

15.4.3.5 Nuclear Regulatory Commission (U.S.) (NRC). NUREG-1220, Rev. 1, "Training Review Criteria and Procedures." NRC: Washington, D.C. January 1993.

15.4.3.6 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, October 1, 2001.

15.4.3.7 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, January 10, 2003.

15.0 MANAGEMENT MEASURES
15.5 PLANT PROCEDURES

15.5.1 CONDUCT OF REVIEW

This section of the revised draft Safety Evaluation Report (DSER) contains the staff's review of procedure information submitted by the applicant in Chapter 15, Section 15.5 of the revised Construction Authorization Request (CAR). The objective of this review is to determine whether the applicant can adequately control potential facility operations in areas to be identified as items relied on for safety (IROFS), by developing, reviewing, approving ,and controlling the implementation of written plant procedures that would protect the workers, the public, and the environment during any potential testing, startup, and operation of the facility. The staff evaluated the applicant's provisions for plant procedures by reviewing Section 15.5 of the revised CAR, other sections of the revised CAR, responses to staff requests for additional information (RAIs) and relevant documents available at the applicant's offices but not submitted by the applicant.

The following regulations apply specifically to the staff's review of the proposed plant procedures:

- Section 70.4 of 10 CFR defines the term "management measures" as including plant procedures.

- Section 70.64(a)(1) of 10 CFR states, in pertinent part, that the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF or the facility) design must be developed and implemented in accordance with management measures, to provide adequate assurance that IROFS will be available and reliable to perform their function when needed.

For the construction approval, in accordance with guidance in NUREG-1718,"Standard Review Plan for the Review of an Application for a Mixed Oxide Fuel Fabrication Facility," Section 15.5.4.3, "Regulatory Acceptance Criteria," the staff review is limited to verifying whether the applicant has adequately committed to establish a process for the production, use, and management control of written plant procedures.

15.5.1.1 Plant Procedures Commitment Description

In revised CAR Section 15.5, the applicant discusses general commitments for plant procedures applicable to the startup, testing, and operations phases of the proposed facility, and states that the MOX Project Quality Assurance Plan (MPQAP) contains the applicant's description of procedures for the design and construction phases. The staff reviewed the MPQAP requirements, in particular Section 5.0, "Instructions, Drawings and Procedures," and determined that they were acceptable for construction activities, including design, procurement and fabrication (Reference 15.5.3.6). The applicant will describe its plant procedures for the facility's proposed startup, testing and operation in more detail in its application for a special nuclear material (SNM) possession and use license.

Revised CAR Section 15.5 provides additional description of the provisions for procedures and identifies four types of plant procedures that would be used to control activities during any facility operations: operating procedures, administrative procedures, maintenance procedures, and emergency procedures. All such procedures would be prepared, issued, used and controlled under the configuration management system and the MPQAP requirements.

Operating procedures would be used to directly control process operations by workstation and control room operators. They would include directions for normal operations, including startup and some testing, operation and shutdown, as well as off-normal conditions, including alarm response. They would also include operating limits and controls, controls to ensure operational safety and hold or check points. Administrative procedures would be used to perform management control activities that support operations, including configuration management (CM), safety, human-system interface, quality assurance (QA), design control, training and qualification, audits and assessment, incident investigations, records and document control, and reporting. Maintenance procedures would address preventive and corrective maintenance, surveillance for calibration, inspection and testing, and functional testing following maintenance. Emergency procedures address the preplanned actions of plant personnel in the event of an emergency.

The applicant describes its commitments during any facility operations to review all plant procedures at least every 5 years to ensure continued accuracy and usefulness. Emergency procedures would be initially reviewed annually and subsequently every 2 years. Additional reviews and modifications of procedures would be based on facility operating experience, incidents and identified inadequacies.

The applicant will develop procedures for test control for the preoperational testing program. These procedures will provide testing criteria for determining when tests will be required and how the activities will be performed. Tests will simulate the most adverse design conditions feasible, and results will be documented, evaluated and acceptability determined by responsible personnel. The applicant commits to developing all required plant procedures prior to receiving any SNM at the site of the proposed facility and to validating the procedures during startup testing of the proposed facility.

15.5.2 EVALUATION FINDINGS

In Chapter 15.5 of the revised CAR, Duke Cogema Stone& Webster (DCS) described its management measures for establishing plant procedures to be used at the proposed facility. Based on that information and the discussion provided in the sections above for plant procedures, the staff finds that the applicant is committed to and would be capable of providing management control necessary to support operation of the proposed facility. Pursuant to 10 CFR 70.64(a)(1), the staff finds that the applicant's proposed plant procedures is a management measure providing adequate assurance that IROFS will be available and reliable to perform their function when needed. The applicant will describe its plant procedures for startup, testing and operation in more detail in its application for an SNM possession and use license. Accordingly, the staff concludes, pursuant to 10 CFR 70.23(b), that the management measures for establishing plant procedures set forth in the MPQAP and the revised CAR is part of a QA program which will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

15.5.3 REFERENCES

15.5.3.1 American Society of Mechanical Engineers (ASME). NQA–1–1994, "Quality Assurance Requirements for Nuclear Facility Applications." ASME: New York, New York. 1994.

15.5.3.2 Code of Federal Regulations, *Title 10, Energy,* Part 70, "Domestic Licensing of Special Nuclear Material."

15.5.3.3 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register:* Vol. 64, No. 146. pp. 41338– 1357. July 30, 1999.

15.5.3.4 ———. "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities." *Federal Register:* Vol. 54, No. 53. pp. 11590–11598. March 21, 1989.

15.5.3.5 Nuclear Regulatory Commission (U.S.) (NRC). Regulatory Guide 1.33, Rev. 2, "Quality Assurance Program Requirements (Operation)." NRC: Washington, D.C. February 1978.

15.5.3.6 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, October 1, 2001.

15.5.3.7 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, January 10, 2003.

15.0 MANAGEMENT MEASURES
15.6 AUDITS AND ASSESSMENTS

15.6.1 CONDUCT OF REVIEW

This section of the revised draft Safety Evaluation Report (DSER) contains the staff's review of the audits and assessment information provided by the applicant in Chapter 15, Section 15.6 of the revised Construction Authorization Request (CAR). The objective of this review is to determine whether the applicant has developed and adequately described a system of audits and assessments that provides reasonable assurance that the principal structures, systems, and components (PSSCs) identified by the applicant at the Mixed Oxide (MOX) Fuel Fabrication Facility's (MFFF or the facility) construction and design stage, and the items relied on for safety (IROFS) to be identified by the applicant in its application for a special nuclear material (SNM) possession and use license, will be available and reliable to perform their safety function when needed. The staff evaluated the applicant's system of audits and assessments by reviewing Chapter 15, Section 15.6 of the revised CAR, other sections of the revised CAR, responses to staff requests for additional information (RAIs) and relevant documents available at the applicant's offices but not submitted by the applicant.

The following regulations apply specifically to the staff's review of the proposed audits and assessments program:

- Section 70.4 of 10 CFR defines the term "management measures" as including an audits and assessments program.

- Section 70.64(a)(1) of 10 CFR states, in pertinent part, that the facility design must be developed and implemented in accordance with management measures, to provide adequate assurance that IROFS will be available and reliable to perform their function when needed.

NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide Fuel Fabrication Facility," Section 15.6.3, "Areas of Review," defines the scope of the construction approval review pertaining to the applicant's planned system of audits and assessments. In reviewing the revised CAR, the staff has evaluated this system and the applicant's provisions for continued adherence to the system.

15.6.1.1 Audits and Assessments - General

In revised CAR Section 15.6.1, the applicant discussed general commitments to perform audits and assessments, and states that they are to be performed in accordance with the applicant's MOX Project Quality Assurance Plan (MPQAP) requirements for structures, systems, and components (SSCs) and associated activities using a graded approach commensurate with their safety significance. The staff reviewed the MPQAP Section 18.0, "Audits," and Section 2.4, "Management Assessments," commitments for audits and assessments and determined that they were acceptable for construction activities (Reference 15.6.3.3). The safety significance of SSCs and their associated activities will be used to determine the frequency and rigor by which they are audited and assessed. The audits and assessments are to provide the applicant's management with feedback on the technical adequacy of SSCs and activities by

evaluating how well the quality assurance (QA) program is being implemented and feedback on the program effectiveness in ensuring that SSCs are properly designed and constructed.

Audits and assessments of SSCs commensurate will be scheduled to provide coverage, consistency and coordination with ongoing work and at a frequency commensurate with the project status and importance of the work. All functional areas performing work controlled by the MPQAP will be audited at least once a year. Results of audits, assessments, surveillances, deficiencies and corrective action reports will be used to determine scope and frequency of functional area audits. Audits will be scheduled to begin as early in the life of the work as practical and will be continued at intervals consistent with the work schedule. External audits of PSSC suppliers will be performed prior to contract placement, with annual supplier evaluations and full audits required every three years. Annual project assessments to determine the overall effectiveness of the QA program will be conducted by the project manager and each functional area performing work on PSSCs will perform an internal management assessment annually. Additional audits and assessments of specific functions will be conducted as directed by management to provide an adequate assessment of compliance and effectiveness.

The applicant commits to conducting its internal and external audits and assessments using procedures in accordance with the approved MPQAP requirements (Reference 15.6.3.3). These procedures will include requirements for scheduling and planning, certification off audit/assessment personnel, development of audit plans and checklists, audit/assessment performance, reporting and tracking of findings to closure and closure of the audit/assessment, and will emphasize timely reporting and correction of findings to prevent recurrence.

The applicant identifies the qualifications and responsibilities of the QA Manager, who will have overall responsibility for managing the QA program including audits and assessments of quality-affecting activities. The QA Verification Manager is directly responsible for ensuring that audits and assessments are conducted in accordance with the MPQAP requirements, including the lead auditor/auditor certification program, audit program management, reporting findings to management, evaluating effectiveness of QA program implementation, approving audit checklists and reports, maintaining the approved suppliers list, and providing input for continuous program improvements.

The applicant describes the training and qualification requirements and responsibilities for audit and assessment personnel. These include lead auditor and auditor training and certification and assessment personnel training appropriate to their activities. Audit and assessment procedures will require that personnel be independent of the activity being audited or assessed, and that they have appropriate authority, freedom and access to make the audit process meaningful and effective, and to properly audit or assess the assigned areas or activities. Checklists will establish acceptance criteria to determine acceptable performance and audit/assessment team determinations, results and reports are reviewed and approved by appropriate management.

Audits and assessments will be conducted using written procedures/checklists and will include detailed walkdowns of plant areas, including out-of-the-way and limited-access areas. If findings result, the deficiencies will be accurately documented for accurate evaluation and timely corrective actions, including immediate correction, where feasible and appropriate. Audit and assessment results will be reviewed by management having responsibility in the area audited/assessed. Audit and assessment findings and recommendations will be documented

and distributed to appropriate management for review ,and response will be required from responsible managers. Audit and assessment results will be tracked by the applicant's QA organization. The data will be analyzed and trended and resultant reports, which indicate quality trends and the effectiveness of management measures, will go to appropriate management for review, response, corrective action, and follow-up.

15.6.1.2 Audits

The applicant describes its requirement for audit team personnel, audit conduct and reporting of results in revised CAR Section 15.6.2. Audit team personnel will be independent of the areas and activities being audited have no direct responsibility for the items they audit. Technical and programmatic audits will performed to evaluate internal project activities using applicable procedures. External suppliers will be evaluated using applicable supplier evaluation procedures. Audit reports will be issued to appropriate management on a timely basis, followup reviews will be performed to verify effective completion of corrective actions for audit findings, and status of open findings are routinely reported to project management. During construction, Internal audits as-built conditions against controlled drawings, specifications, and procedures based on committed construction codes and standards.

15.6.1.3 Assessments

The applicant's description and commitments for assessments include appropriate requirements as discussed in Section 15.6.1.1, above. In particular, annual project assessments to determine the overall effectiveness of the QA program will be conducted by the project manager and each functional area performing work on PSSCs will perform an internal management assessment annually. Additional audits and assessments of specific functions will be conducted as directed by management to provide an adequate assessment of compliance and effectiveness.

15.6.1.4 Provisions for Continuing Assurance

The applicant's provisions for adhering to its planned system of audits and assessments are described in revised CAR Section 15.6.4, and include maintaining the applicant's QA program current through deactivation of the proposed facility. Appropriate changes to the QA program and procedures for audits and assessments will be made due to reorganizations, revised activities, lessons learned, changes to applicable regulations, and program improvements. The applicant also committed to update the system of audits and assessments to reflect any changes to the proposed facility made between submittal of the revised CAR and submittal of the application for a license to possess and use SNM.

15.6.2 EVALUATION FINDINGS

In Chapter 15.6 of the revised CAR, Duke, Cogema, Stone & Webster (DCS) described its planned system for conducting audits and assessments on PSSCs and IROFS at the proposed facility. Based on that information and the discussion provided in the sections above for audits and assessments, the staff finds that the applicant has adequately described its system for audits and assessments. Pursuant to 10 CFR 70.64(a)(1), the staff finds that the applicant's proposed audits and assessments system is a management measure providing adequate

assurance that IROFS will be available and reliable to perform their function when needed. Accordingly, the staff concludes, pursuant to 10 CFR 70.23(b), that the system for audits and assessments set forth in the MPQAP and the CAR is part of a QA program which will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

15.6.3 REFERENCES

15.6.3.1 Code of Federal Regulations, *Title 10, Energy*, Part 70, "Domestic Licensing of Special Nuclear Material."

15.6.3.2 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register:* Vol. 64, No. 146. pp. 41338-41357. July 30, 1999.

15.6.3.3 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, October 1, 2001.

15.6.3.4 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, January 10, 2003.

15.0 MANAGEMENT MEASURES
15.7 INCIDENT INVESTIGATIONS

15.7.1 CONDUCT OF REVIEW

This section of the revised draft Safety Evaluation Report (DSER) contains the staff's review of the system for incident investigations referenced by the applicant in Chapter 15, Section 15.7.1 of the revised Construction Authorization Request (CAR). The objective of this review is to determine whether the applicant has developed and adequately described a process for the systematic investigation of incidents, assignment and acceptance of corrective actions, and follow-up to ensure completion of the actions. The staff evaluated the applicant's proposed system by reviewing Chapter 15, Section 15.7 of the revised CAR, Mixed Oxide Project Quality Assurance Plan (MPQAP) Section 16, responses to staff requests for additional information (RAIs) and relevant documents available at the applicant's offices but not submitted by the applicant.

The following regulations apply specifically to the staff's review of the proposed system for conducting incident investigations:

- Section 70.4 of 10 CFR defines the term "management measures" as including incident investigations.

- Section 70.64(a)(1) of 10 CFR states, in pertinent part, that the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF or the facility) design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety (IROFS) will be available and reliable to perform their function when needed.

With respect to the applicant's proposed system for conducting incident investigations, NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide Fuel Fabrication Facility," Section 15.7.4.3, limits the staff's CAR review to verifying whether the applicant has committed to establishing a system to adequately investigate incidents. Such as system includes provisions for the assignment and acceptance of corrective actions, and follow-up measures to ensure completion of corrective actions.

15.7.2.1 Incident Investigation and Corrective Action Process and Administration

In revised CAR Sections 15.7.1 and 15.7.2, the applicant discussed its commitments and process to perform incident investigation and corrective action, and states that the process currently in use during design and construction phases of the proposed facility is as described in the applicant's MPQAP Section 16, "Corrective Action." MPQAP Section 16 was previously reviewed and approved by the staff (Reference 15.7.3.9). MPQAP Section 16.0 contains the applicant's system for identifying, classifying, followup, closure and trending of conditions adverse to quality, and for preparing significant event reports. The staff has verified that this system is adequate for ensuring that proper corrective action would be taken during any construction activities, including design, procurement and fabrication (Reference 15.7.3.9). In revised CAR Section 15.7.2, the applicant commits to modify this process prior to any facility startup testing to include the additional specific actions that would be needed to support an operating facility.

The applicant's description in revised CAR Section 15.7.1 of the incident investigation and corrective action process for design, construction and operations includes management controls to promptly identify incidents/findings, evaluate the need to stop work, assign investigation teams, significance and root cause evaluations and corrective action planning, management approval, implementation, completion and tracking, as well as tracking and evaluation for adverse trends.

Corrective action process administration is discussed in revised CAR Section 15.7.2. The incident investigation and deficiencies corrective action process will be administered by the applicant's QA organization during the design and construction phases of the proposed facility. In its application for a special nuclear material (SNM) possession and use license, the applicant commits to providing a detailed description of how the incident investigations process would work during any operation of the proposed facility. Such a description will be expected to address the prompt investigation of incidents, the use of qualified investigative teams, monitoring and documenting corrective actions, investigating team plans, methodologies, personnel qualifications and independence and appropriate documentation and records requirements.

15.7.2 EVALUATION FINDINGS

In Chapter 15.7 of the revised CAR, Duke, Cogema, Stone & Webster (DCS) described its planned system for performing incident investigations relevant to principal structures, systems and components (PSSCs) and associated activities during the construction of the proposed facility, including design, procurement and fabrication activities. Based on that information and the discussion provided in the sections above for audits and assessments, the staff finds that the applicant has adequately described its system for performing incident investigations. Pursuant to 10 CFR 70.64(a)(1), the staff finds that the applicant's proposed incident investigations system is a management measure providing adequate assurance that IROFS will be available and reliable to perform their function when needed. Accordingly, the staff concludes, pursuant to 10 CFR 70.23(b), that the system for incident investigations set forth in the MPQAP and the revised CAR is part of a QA program which will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

15.7.3 REFERENCES

15.7.3.1 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register* : Vol. 64, No. 146. pp. 41338–41357. July 30, 1999.

15.7.3.2 Code of Federal Regulations, *Title 10, Energy,* Part 70, "Domestic Licensing of Special Nuclear Material."

15.7.3.3 Department of Energy (U.S.) (DOE). DOE–STD–1010–92, "Guide to Good Practices for Incorporating Operating Experiences." DOE: Washington, D.C. July 1992.

15.7.3.4 ———. DOE–NE–STD–1004–92, "Root Cause Analysis Guidance Document." DOE: Washington, D.C. February 1992.

15.7.3.5 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register:* Vol. 64, No. 146. pp. 41338-41357. July 30, 1999.

15.7.3.6 Nuclear Regulatory Commission (U.S.) (NRC). Information Notice 96–28, "Suggested Guidance Relating to Development and Implementation of Corrective Action." NRC: Washington, D.C. May 1996.

15.7.3.7 _____. NUREG/CR–4616, "Root Causes of Component Failures Program: Methods and Applications." NRC: Washington, D.C. December 1986.

15.7.3.8 ———. NUREG/CR–5665, "A Systematic Approach to Repetitive Failures." NRC: Washington, D.C. February 1991.

15.7.3.9 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, October 1, 2001.

15.7.3.10 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, January 10, 2003.

15.0 MANAGEMENT MEASURES
15.8 RECORDS MANAGEMENT

15.8.1 CONDUCT OF REVIEW

This section of the revised draft Safety Evaluation Report (DSER) contains the staff's review of the facility records management system provided by the applicant in Chapter 15, Section 15.8 of the revised Construction Authorization Request (CAR). The objective of this review is to verify that the applicant has developed and adequately described a facility records management system that complies with NRC requirements. The staff evaluated the applicant's facility records management system by reviewing Chapter 15, Section 15.8 of the revised CAR, other sections of the revised CAR, responses to staff requests for additional information (RAIs) and relevant documents available at the applicant's offices but not submitted by the applicant.

The following regulations apply specifically to the staff's review of the proposed records management system:

- Section 70.4 of 10 CFR defines the term "management measures" as including a records management system.

- Section 70.64(a)(1) of 10 CFR states that the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF or the facility) design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety (IROFS) will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide Fuel Fabrication Facility," Section 15.8.3, "Areas of Review," defines the scope of the construction approval review of the applicant's facility records management system to include: (1) the process whereby records are specified, created, verified, categorized, indexed, inventoried, protected, stored, maintained, distributed, and deleted or preserved; (2) the handling and control of various kinds of records and the methods of recording media that comprise the records, including contaminated and classified records; and (3) the physical characteristics of the record storage facilities with respect to the preservation and protection of the records for their designated lifetimes.

The applicant's description of its facility records management system, in revised CAR Section 15.8, addresses commitments for the records management program, including record generation, receipt, storage, preservation, safekeeping, correction, retrieval, and disposition, for program changes and provisions for continuing adequate records management.

15.8.1.1 Records Management Program

In revised CAR Section 15.8.1, the applicant describes it's facility records management system, and states that the system for controlling records management responsibilities and the generation, review, approval, classification, verification, indexing, storage, protection, maintenance, correction, retrieval and disposition of quality assurance (QA) records will be in

accordance with the MOX Project Quality Assurance Plan (MPQAP) requirements. The staff reviewed the MPQAP Section 17.0, "Quality Assurance Records," commitments for audits and assessments and determined that they were acceptable for construction activities at the proposed facility (Reference 15.8.3.6). Section 17.0 of the MPQAP, "Quality Assurance Records," commits the applicant to adhere to the requirements of 10 CFR Part 50, Appendix B, Criterion 17, "Quality Assurance Records," and Basic Requirement 17 and Supplement 17S-1 of NQA-1-1994 Part I, as revised by Regulatory Guide 1.28 (Rev.3). The applicant did not request to be excepted from any of these requirements. The staff reviewed the applicant's commitments and the description of the QA program for records in accordance with NUREG-1718 and compared them to the applicable requirements of 10 CFR Part 50, Appendix B, and the NQA-1 provisions. The staff reviewed the MPQAP description of the Mixed facility QA records management system and verified that MPQAP Section 17.0 meets the requirements of 10 CFR Part 50, Appendix B, and NQA-1.

The applicant further describes the records management system in revised CAR Section 15.8.1, including applicable project procedures, dual facility storage and fireproof backup tape storage for electronic data management system (EDMS), and use of fireproof storage for other documents such as radiographs, microfilm, etc. The procedures control the generation of records, their review and approval as records, receipt process, storage, preservation and safekeeping. Records requiring correction or revision will be retrieved by authorized individuals in accordance with the applicable procedures. Original records will be retained and the revision processed per the applicable project procedures. Records file folders, and interfacing links to associated documents/records, will be structured to ensure timely retrievability of records. All "lifetime" QA records will be stored for the period of time in which the proposed facility may operate.

15.8.1.2 Records Management Program Changes

The applicant's discussion included the requirements that routine audits, surveillances and assessments of document control and records management will be performed to evaluate the implementation of the program. Findings and observations from such oversight functions and other monitoring activities may result in program improvements.

15.8.1.3 Continuing Records Management Provisions

The applicant's provisions for ensuring that the continuing adequacy of its records management system includes commitments to keep the program procedures current. The records management procedures will be revised based on lessons learned during implementation, corrective actions from audits, surveillances, or assessment, improvements based on trend analysis, and changes due to regulations, commitments, reorganizations, revised schedules or program improvements. The applicant committed to update the facility records management system to reflect any changes to the proposed facility made between submittal of the revised CAR and submittal of the application for a license to possess and use special nuclear material (SNM).

15.8.2 EVALUATION FINDINGS

In Chapter 15.8 of the revised CAR, DCS described its planned records management system to be used at the proposed facility. Based on that information and the discussion provided in the sections above for the records management system, the staff finds that the applicant has adequately described its system for records management. Pursuant to 10 CFR 70.64(a)(1), the staff finds that the applicant's proposed records management system is a management measure providing adequate assurance that IROFS will be available and reliable to perform their function when needed, and that appropriate records would be maintained by or under the control of Duke, Cogema, Stone & Webster (DCS) throughout the operating life of the proposed facility, if the Nuclear Regulatory Commission (NRC) authorizes its operation. Accordingly, the staff concludes, pursuant to 10 CFR 70.23(b), that the records management system set forth in the MPQAP and the revised CAR is part of a QA program which will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

15.8.3 REFERENCES

The requirements for records management are addressed in the following:

15.8.3.1 Code of Federal Regulations, *Title 10, Energy*, Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations."

15.8.3.2 –-——*, Title 10, Energy*, Part 20, "Standards for Protection Against Radiation."

15.8.3.3 ———, *Title 10, Energy*, Part 21, "Reporting of Defects and Noncompliance."

15.8.3.4 ———, *Title 10, Energy*, Part 25, "Access Authorization for Licensee Personnel."

15.8.3.5 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register:* Vol. 64, No. 146. pp. 41338-41357. July 30, 1999.

15.8.3.6 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, October 1, 2001.

15.8.3.7 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, January 10, 2003.